article was effective as a natural remedy for growth, reproduction, rejuvenation, and longevity, as a specific for otherwise incurable maladies, to relieve women during the menopause, to restore normality to the growth of retarded children, to produce a general well-being, to prevent fatigue from prolonged intellectual work, to stimulate the appetite, to stimulate all bodily functions, to cure heart patients, to alleviate suffering from nervous and vascular disorders, to cure Parkinson's disease, and to cure cancer in chickens and prolong the life of pigs, rats, and guinea pigs; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–15–55. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4784. Penicillin sodium salt. (F. D. C. No. 37010. S. No. 63–084 L.)

QUANTITY: 190 vials at Decatur, Ill.

SHIPPED: On an unknown date, from Brooklyn, N. Y.

LABEL IN PART: (Vial) "200,000 Oxford Units Penicillin (Sodium Salt) * * * Expiration Date: August – 1947 087040–B."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the labeled potency of penicillin sodium.

LIBELED: 7–20–54, S. Dist. Ill.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, penicillin sodium, the name of which is recognized in the United States Pharmacopeia, an official compendium, and while held for sale its strength differed from the standard set forth in the compendium; 502 (a)—the label statement "200,000 Oxford Units Penicillin (Sodium Salt)" was false and misleading as applied to a product which contained less than the labeled potency; and 502 (l)—the drug purported to be and was represented as a drug composed partly of a kind of penicillin, and it was from a batch with respect to which a certificate or release, as required by regulations, was not in effect.

DISPOSITION: Lincoln Laboratories, Inc., claimant, filed an answer averring that the article was not misbranded while held for sale after shipment in interstate commerce as alleged in the libel, but was held by the claimant for investigational and research purposes only. Subsequently, written interrogatories served upon the claimant by the Government were answered.

The case came on for trial before the court without a jury on 12–6–55, and on 12–16–55, the court, having found that the claimant and the Government had agreed that the product should be destroyed, ordered that the product be released to the claimant for destruction. On 1–5–56, the court entered an order dismissing the libel with prejudice on the grounds that, since the subject matter thereof had been destroyed, all questions in the case had become moot.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4785. Whole pituitary tablets. (F. D. C. No. 36371. S. No. 60–144 L.)

QUANTITY: 104,200 tablets in 2 drums at Atlanta, Ga.

SHIPPED: 11–20–53, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Drum) "Special Tablets Enteric SC Brown Code C.D.A.T. Lot No.: 8996 Formula contains at time of manufacture: Whole Pituitary Po 3 gr. per tablet."

LIBELED: 2–3–54, N. Dist. Ga.; libel amended 3–16–54.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use; and 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and prior to dispensing, its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Crews Drug Co., Inc., Atlanta, Ga., claimant, filed an answer denying that the article was misbranded as alleged and claiming that the article was exempt from the requirements of 502 (f) (1) under the provisions of 503 (b) (2) since it was to be dispensed only upon the prescription of a physician. Thereafter, on 3–16–54, the Government filed a motion to strike that portion of the claimant's answer claiming an exemption for the article, and in support of such motion, it claimed that the defense relied upon was insufficient in law. A motion was filed also to amend the libel to include the charge of misbranding within the meaning of 503 (b) (4). The motion to amend the libel was granted on 3–16–54.

The claimant filed a motion to amend its answer to include the claim that the article was also exempt from the labeling requirements of the Act by reason of the provisions of 503 (b) (1) (B). The motion was granted on 4–20–54. On 9–20–54, the Government's motion to strike was granted, there being no objection on the part of the claimant.

Subsequently, interrogatories were served upon the claimant by the Government and were answered. On 12–7–55, the court, upon motion of the Government and with the consent of the claimant, entered a decree condemning the article and ordering its destruction.

4786. Apiol and ergotin compound. (F. D. C. No. 38176. S. No. 21–585 M.)

QUANTITY: 17 pkgs., 24 24-capsule boxes each, at Philadelphia, Pa.

SHIPPED: 4–1–54, from Brooklyn, N. Y., by Jamco Co.

LABEL IN PART: (Box) "Penhurst Apiol and Ergotin Compound 24 * * * Each capsule contains: Apiol 5 Min. Oil Pennyroyal 1/2 Min. Ergotin 4 Gr. Aloin 1/8 Gr. Vegetable Oil O. S. 10 Min."

LIBELED: 6–2–55, E. Dist. Pa.

CHARGE: 503 (b) (4)—the article was a drug subject to 503 (b) (1), and when shipped its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8–3–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4787. Quinine hydrochloride. (F. D. C. No. 33786. S. No. 49–431 L.)

INDICTMENT RETURNED: 12–20–54, S. Dist. N. Y., against Sidney J. Cohen, New York, N. Y.

ALLEGED VIOLATION: The indictment alleged that, on or about 8–25–52, while a quantity of *quinine hydrochloride* was being held for sale, the defendant mutilated, destroyed, and removed a portion of the labeling displayed upon the drum containing the article, which acts resulted in the article being misbranded.

CHARGE: 502 (b) (1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502 (e) (1)—the article failed to bear a label containing the common or usual name of the

*See also No. 4785.